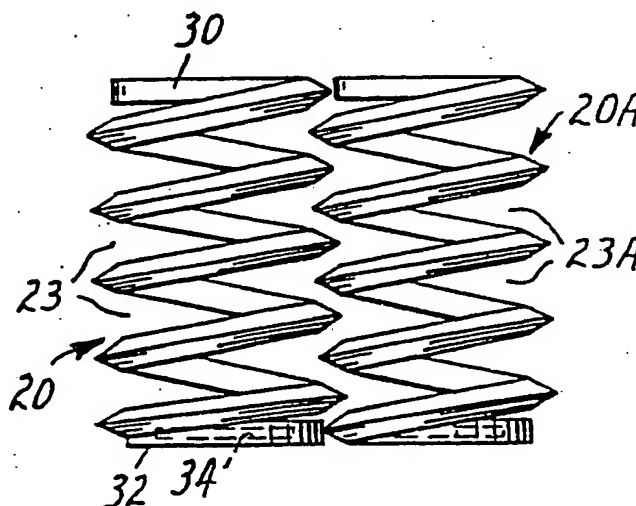


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US90/05312 (22) International Filing Date: 18 September 1990 (18.09.90) (30) Priority data: 432,087 6 November 1989 (06.11.89) US (71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 1240 South Loop Road, Alameda, CA 94501 (US). (72) Inventor: RAY, Charles, D. ; 19550 Cedarhurst, Wayzata, MN 55391 (US). (74) Agent: MEYER, Sheldon, R.; Fliesler, Dubb, Meyer & Lovejoy, Four Embarcadero Center, Suite 400, San Fran- cisco, CA 94111-4156 (US).		(81) Designated States: AT (European patent), AU, BE (Euro- pean patent), CA, CH (European patent), DE (Euro- pean patent)*, DK (European patent), ES (European pa- tent), FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent). Published <i>With international search report.</i>

(54) Title: SURGICALLY IMPLANTING THREADED FUSION CAGES BETWEEN ADJACENT LOW-BACK VERTEBRAE BY AN ANTERIOR APPROACH

**(57) Abstract**

When an intervertebral fusion is required, and the disc space is unusually large, that disc space can be preserved by surgically implanting a pair of relatively large male-thread fusion cages (20, 20A) with their threads (13) overlapping. Because of their large size, such fusion cages (20, 20A) should be implanted by an anterior approach to the lower back. When each of the cages is made of a shape-retaining helix (22) of wire that is hollow within the helix (22) and has openings (23) between adjacent turns, the cages (20, 20A) can be removed after the adjacent vertebrae have become fused together and without disrupting that fusion, thus guarding against possible rejection of the cages (20, 20A) by the patient's body. The anterior approach and scaled-down fusion cages (20, 20A) may be used in cervical spine fusions.

SURGICALLY IMPLANTING THREADED FUSION CAGES BETWEEN
ADJACENT LOW-BACK VERTEBRAE BY AN ANTERIOR APPROACH

5

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of copending U.S. Patent Application S.N. 07/259,031, filed October 17, 1988 and entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT". The present application also is related to an application entitled "SURGICAL METHOD AND APPARATUS FOR FUSING ADJACENT BONE STRUCTURES", assigned U.S. Application S.N. 07/432,088 and filed on November 6, 1989.

15

BACKGROUND OF THE INVENTION

Field of the Invention

The invention concerns method and apparatus for fusing two adjacent vertebrae of the lower spine by an anterior approach and also concerns V-thread and other male-thread fusion cages that are specially adapted for situations requiring the anterior approach.

Description of Related Art

25

Many bone fusion devices are currently available. Some of these are described by the following publications.

30

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and

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U.S. Pat. No. 2,537,070 (Longfellow) shows in Fig. 2 a "reinforce 7" that is much like Bagby's fusion basket.

5 Vich, J. Nerosurg., Vol 63, pp 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft.

10 Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertebral cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with
15 instruments especially developed for this purpose (p. 750).

Vich's Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding.

20 Vich also says:

When grafts with a diameter of 14 mm were used, we sometimes threaded the receiving bed with a die-stock of 13 mm to facilitate the insertion (p. 751).

25 SUMMARY OF THE INVENTION

Prior art fusion devices such as described above are not suitable for the requirements for which the present invention has been developed.

30 A large majority of patients requiring intervertebral fusions have narrowing of the disc space, typically 10 mm or less in the lower back.

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When the bores overlap, the bit used in drilling the second bore has a tendency to drift toward a common center. The bit also tends to wander because the consistency of cancellous bone of the vertebral bodies is similar to wet balsa wood while that of the hard shell is similar to about 1.5 veneer of white oak.

The present invention answers the above-outlined problems by an anterior approach to the lower back. The invention also concerns novel male-thread fusion cages and a method of implanting them that allows their threads to overlap, while assuring that the axes of the implanted cages are parallel. The novel male-thread fusion cages resist being forced out of position and toward the center of the disc space due to swelling of tissues lateral to the cages.

One of the novel male-thread fusion cages has the valuable attribute of being removable after the adjacent vertebrae have become fused together, and without disrupting that fusion, thus guarding against possible rejection of the implant by the patient's body. The removable fusion cage is made of shape-retaining cylindrical helix of wire that is hollow within the helix and has openings between adjacent turns. Those openings preferably are great enough to allow the wire of an identical fusion cage to penetrate to the hollow of the cage when the two cages are side-by-side with their axes parallel. Secured to each end of the helix is a device through which torque can be simultaneously transmitted equally to both ends of the helix, thus permitting it to be inserted into a threaded bore without binding. The torque-

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The novel cylindrical helix and two other male-thread fusion cages of the invention are illustrated in the drawing. When the outside diameter of their threads are 20 mm, pairs can be implanted with their parallel axes separated by only about 15 to 16 mm.

As noted above, fusion cages having threads that are 20 mm in diameter should be implanted by an anterior approach to the lower back. The anterior approach, even though safe, is complicated by the need to approach the lower back through the abdomen, usually by passing around and not through the peritoneal sac. Major vessels and autonomic nerves which hug that anterior aspect of the vertebral bodies must be pulled aside. The invention provides a novel template-holding retractor for doing so in a manner which is practical and safe when carefully performed.

THE DRAWING

In the drawing, all figures of which are schematic,

Fig. 1 is an isometric view of a preferred V-thread fusion cage as disclosed in parent U.S. Patent Application S.N. 07/259,031;

Fig. 2 is an exploded isometric view of a first male-thread fusion cage of the present invention, an insert for blocking one lateral side of the cage, and a pair of end caps;

Fig. 3 shows the side-by-side implanted relationship of a pair of the fusion cages of Fig. 2;

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then been machined in that external surface, thus creating perforations 14 in the valley between adjacent turns of the thread, each perforation extending between a pair of lands 15 and 15A. One
5 land 15, which is wider than the other land 15A, is to be positioned adjacent the edge of the disc to prevent disc tissue from growing into the cage. Each end of each land has been machined to form a recess 16 enabling an end cap (not shown) to fit flush with the
10 end of the fusion cage.

In Fig. 2, a first male-thread fusion cage 20 of the present invention has been formed from triangular wire 21 as a shape-retaining cylindrical helix 22 that has openings 23 between adjacent turns.
15 After the fusion cage 20 and an identical fusion cage 20A have been implanted side-by-side as in Fig. 3, indentations 24 of an insert 25 snap-fit into the openings 23, thus blocking one lateral side of each cage while the unblocked openings 23 at the top and
20 bottom of each helix afford perforations through which bone can grow.

Welded to the leading end of the helix 22 is a first ring 30 that has a small hexagonal opening 31. Welded to the trailing end of the helix 22 is a second
25 ring 32 that has a large hexagonal opening 33. Behind the large hexagonal opening 33 is a slot 34 to receive an end cap 36 that is formed with a small hexagonal opening 38.

To implant the male-thread fusion cage 20
30 into a bore having a mating thread (not shown), a tool (not shown) simultaneously fits into the hexagonal openings 31 and 33 of the first and second rings 30

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20A, respectively, are in contact, thus permitting bone to grow therebetween.

Fig. 5 shows a second male-thread cage 50 of the invention that can be formed from a solid metal cylinder by drilling six small holes 51 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. A V-thread (not shown) is machined into the external surface of the cylinder, thus opening perforations through the valley of the V-thread at each crossing with one of the small holes 51. A large hole is drilled on the axis of the cylinder and broached to leave a flat-sided hollow 54 that communicates with said perforations except at the wall 55 at the flat side of the hollow 54. A flat side face 56 at its outer surface gives the wall a uniform thickness. The external V-thread permits the fusion cage 50 and an identical fusion cage 50A (indicated by phantom lines) to be screwed into parallel threaded bores such that the cylinders generated by the crowns of the V-thread of the two cages overlap, thus permitting the two cages to be closer together than would otherwise be feasible.

Fig. 6 shows a third male-thread fusion cage 60 that can be made in the same way as the cage 10 of Fig. 1, followed by cutting away one land to produce a C-shaped cross section that has one remaining land 61. The fusion cage 60 can be screwed into a threaded bore by first inserting a rod 62 having a projection 63 that is formed with a thread 64. A C-shaped insert 66 forces the thread 64 to the position shown at which it completes the thread of the fusion cage. The rod 62

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drilled through the first opening 91 of the first template 90. The diameters of the circular opening 103 is selected to ensure that the enlarged bore penetrates through the cortical shells of the vertebrae 81 and 82.

The third template 110 of Fig. 11 has an index pin 112 that fits into a pilot bore that has been drilled through the second opening 92 of the first template and a circular opening 113 that acts as a guide for a tap by which a female thread can be formed in the enlarged bore that has been drilled through the opening 103 of the second template 100. The diameter of the circular opening 113 is selected to ensure that the female thread penetrates into the cancellous bone of each of the vertebrae 81 and 82.

The fourth template 120 of Fig. 12 has an index pin 123 that fits into a bore after it has been threaded through the circular opening 123 of the third template 110. The fourth template also has a circular opening 124 which acts as a guide for enlarging a pilot bore that has been drilled through the second opening 92 of the first template 90. The diameter of the circular opening 124 equals that of the circular opening 103 of the second template.

The fifth template 130 of Fig. 13 has an index pin 133 that fits into the same threaded bore as did the pin 123 of the fourth template 120. The fifth template has a circular opening 134 that acts as a guide for the same tap as was inserted through the circular opening 113 of the template 110.

After screwing a pair of male-thread fusion cages into the threaded bores formed using the third

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What is claimed is:

1. A fusion cage system adapted for being implanted in and promoting fusion with respect to one or more bone structures when bone-growth-inducing substance is packed into the fusion cage system comprising:

a first fusion cage which has a first outside dimension and a first internal cavity adapted to be packed with the bone-growth-inducing substance;

a second fusion cage which has a second outside dimension and a second internal cavity adapted to be packed with the bone-growth-inducing substance;

at least one of the first fusion cage and the second fusion cage including means for allowing said first and second fusion cages to be positioned adjacent each other such that an outside dimension of the combination of the first fusion cage positioned adjacent the second fusion cage is less than the sum of the first outside dimension and the second outside dimension.

2. The fusion cage system of claim 1 wherein:

said first fusion cage and said second fusion cage include first and second means respectively for allowing immediate contact between the one or more bone structures and the bone-growth-inducing substance.

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9. The fusion cage system of claim 1
wherein said first fusion cage includes a "C"-shaped
cylindrical body and said allowing means includes an
opening in said "C"-shaped cylindrical body that
5 communicates with said first internal cavity.

10. A fusion cage system adapted for being
implanted in and promoting fusion with respect to one
or more bone structures when bone-growth-inducing
10 substance is packed into the fusion cage system
comprising:

a first fusion cage which is substantially
cylindrical in shape and which has a first outside
diameter and a first internal cavity adapted to be
15 packed with the bone-growth-inducing substance;

a second fusion cage which is substantially
cylindrical in shape and which has a second outside
diameter and a second internal cavity adapted to be
packed with the bone-growth-inducing substance; and

20 said second fusion cage including means for
allowing said first fusion cage to be rotatably
positioned with respect to the one or more bone
structures and with respect to the second fusion cage
such that the outside dimension of the combination of
25 the first fusion cage positioned adjacent the second
fusion cage is less than the sum of the first outside
diameter and the second outside diameter.

11. The fusion cage system of claim 10
30 wherein:

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the one or more bone structures and with respect to the first fusion cage previously implanted with respect to the one or more bone structures.

5 13. The fusion cage system of claim 12 wherein:

 said first fusion cage and said second fusion cage include first and second means respectively for allowing immediate contact between the one or more
10 bone structures and the bone-growth-inducing substances.

 14. A fusion cage system adapted for being implanted in and promote fusion with respect to one or
15 more bone structures when bone growth inducing substance is packed into the fusion cage system comprising:

 a first fusion cage which is comprised of a first helical structure having a first inner surface
20 which defines a first internal cavity, which first helical structure including a plurality of spaced apart first turns, said first helical structure having a first outer diameter;

 a second fusion cage which is comprised of a second helical structure having a second inner surface
25 which defines a second internal cavity, said second helical structure including a plurality of spaced apart second turns, said second helical structure having a second outside diameter;

 30 wherein the spacing of the first turns and the spacing of the second turns is such that the first turns can intermesh with the second turns when the

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17. The fusion cage system of claim 14 including first means for blocking a portion of the space between the first turns at a first location diametrically opposite from where the first turns intermesh with the second turns; and

second means for blocking a portion of the space between the second turns at a second location diametrically opposite from where the second turns intersect with the first turns so as to prevent tissue ingrowth where blocking occurs.

18. The fusion cage system of claim 14 wherein said first blocking means includes means for snapping into the space between the first turns, and the second blocking means includes means for snapping into the space between the second turns.

19. The fusion cage system of claim 14 including means for securing the first helical structure to the second helical structure.

20. The fusion cage system of claim 14 wherein said first fusion cage has a first axis about which said first helical structure is symmetrical and said second fusion cage has a second axis about which said second helical structure is symmetrical, such that with the first turns intermeshed with the second turns and with the first axis and the second axis separated by a distance, the distance is less than the first outer diameter or the second outer diameter.

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such that a dimension of the fusion cage system with the first fusion cage positioned adjacent the second fusion cage is less than the sum of the first outer diameter and the second outer diameter.

5 22. The fusion cage system of claim 21 wherein:

 the first and second perforation means includes first and second means, respectively, for providing immediate contact between the one or more
10 bone structures and bone-growth-inducing substance packed into the first and the second internal cavities.

 23. The fusion cage system of claim 21:
15 wherein the second fusion body includes a wall formed along the wall of a cord of the second cylindrical body.

 24. The fusion cage system of claim 21
20 wherein the first wall is imperforate.

 25. The fusion cage system of claim 23 wherein the first and the second walls are imperforate.

25 26. The fusion cage system of claim 21 wherein the first cylindrical body is imperforate at a location substantially opposite from the first wall.

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first perforation means defined in said first valleys for communication between the first internal cavity and the first outer surface;

5 a second helical thread formed in the second outer surface of the second cylindrical body, which second helical thread includes a plurality of turns having second valleys formed between said turns and second perforation means defined in said second valleys for communication between the second internal
10 cavity and the second outer surface, such that with the first fusion cage implanted, the second fusion cage be screwed into the place with the second wall adjacent the first wall such that a dimension of the fusion cage system with the first fusion cage
15 positioned adjacent the second fusion cage is less than the sum of the first outer diameter and the second outer diameter.

30. A fusion cage system adapted for being
20 implanted in and promote fusion with respect to one or more bone structures when gone-growth-inducing substance is packed into the fusion cage system comprising:

25 a first fusion cage which is comprised of a first C-shaped cylindrical body which had a first inner surface which defines a first internal cavity and a first outer surface with a first outer diameter and a first opening communicating with the first internal cavity, said first outer surface defining a
30 first helical thread which includes a plurality of first turns with first valleys defined between said

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outer surface which defines part of a third helical thread which can mate with the first helical thread on the first outer surface.

5 33. The fusion cage system of claim 30 wherein said second cylindrical body is C-shaped and said second outer surface has a second opening which communicates with said second internal cavity such that the first and second fusion cage can be implanted
10 with the first opening facing the second opening.

 34. The fusion cage system of claim 30 including a first removable insert means positionable in either of said first opening and said second
15 opening for closing either of said first opening and said second opening and for allowing selectively the first fusion cage and the second fusion cage to be implanted and said first removable means then removed, said first insert means including a third outer
20 surface which defines a third helical thread which can mate with either the first helical thread on the first outer surface or the second helical thread on the second outer surface.

25 35. The fusion cage system of claim 30 wherein the first cylindrical body has a first axis and the second cylindrical body has a second axis and with the first fusion cage implanted adjacent the second fusion cage the distance between the first axis
30 and the second axis is less than either of the first outer diameter or the second outer diameter.

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position between and engaging the two adjacent bone structures, a second internal cavity adapted to be packed with bone-growth-inducing substance and second means for communicating the bone structures with the second internal cavity;

5 said first cylindrical fusion cage including means for allowing the first and second fusion cages to be positioned adjacent each other so that a dimension of the fusion cage system with the first cage positioned adjacent the second cage is less than the second distance.

10 38. The fusion cage system of claim 37 wherein the said allowing means includes means for intermeshing the first fusion cage with the second fusion cage.

15 39. A method for surgically implanting between two adjacent vertebrae a pair of male-thread hollow fusion cages, each of which is perforated in the valley between adjacent turns of the threads of the cages, said method comprising the steps of:

20 (a) displacing soft tissues safely to the side of the vertebrae by centering a template-holding retractor over the vertebrae and temporarily anchoring the retractor to the vertebrae;

25 (b) attaching to said retractor a first template having at least one opening to act as a guide for a pilot drill;

30 (c) using the first template as a guide, drilling first and second pilot bores in a disc located between the adjacent vertebrae;

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43. The method as defined in claim 42 wherein each of the fusion cages has an imperforate area and is rotated in step (f) to align those imperforate areas laterally outwardly and between the vertebrae.

44. The method as defined in claim 39 and using an anterior approach to the lower back which passes around the peritoneal sac.

45. The method of claim 39 including the steps of:
removing the cages once fusion between the two adjacent vertebrae has occurred.

46. A fusion cage adapted for promoting the fusion with one or more bone structures when bone-growth-inducing substance is packed into the fusion cage, comprising:

a helical structure having an inner surface which defines an internal cavity;
said helical structure having an outer surface pointing in a direction away from the internal cavity and adapted for contacting the one or more bone structures;

said helical structure defining a plurality of turns;
a plurality of openings defined between said turns such that there is at least one opening between adjacent turns;

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48. A fusion cage of claim 47 including
first and second ends defined by the helical structure
which communicate with said internal cavity; and
at least one end cap for covering at least
5 one of said first and said second ends, which end cap
is transparent to x-rays and magnetic signals.

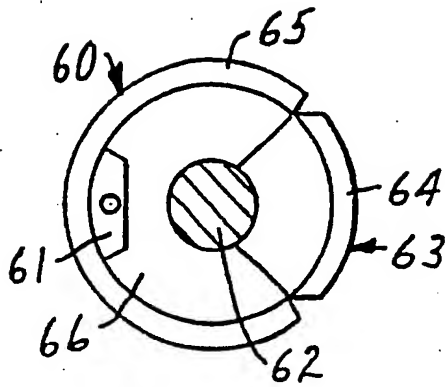


FIG. 6

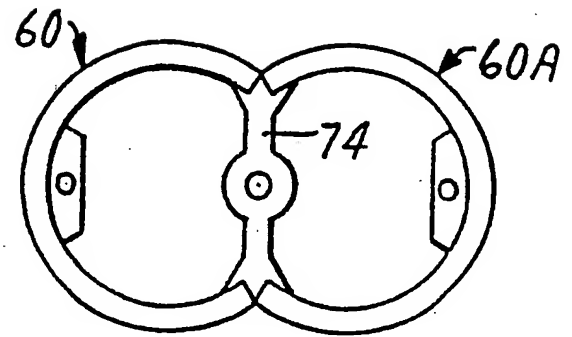


FIG. 7

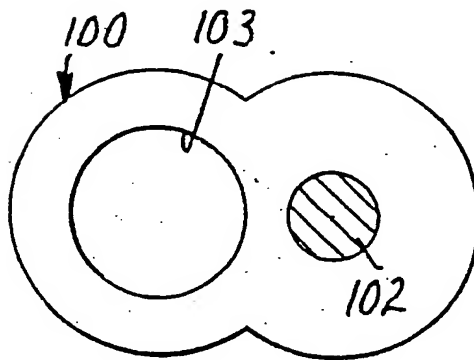


FIG. 10

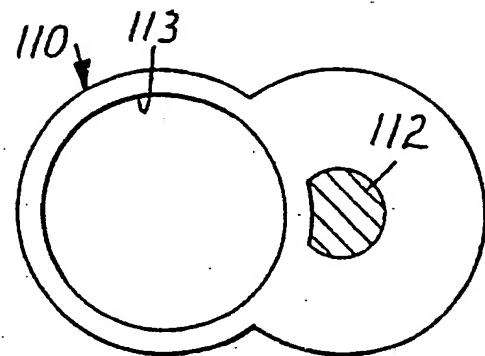


FIG. 11

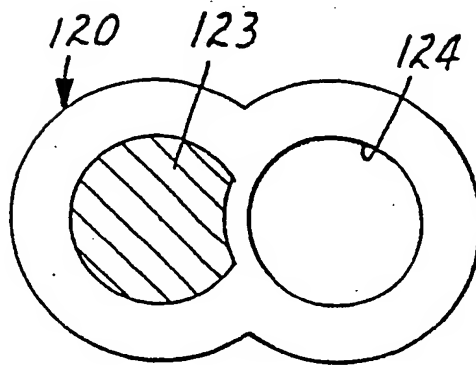


FIG. 12

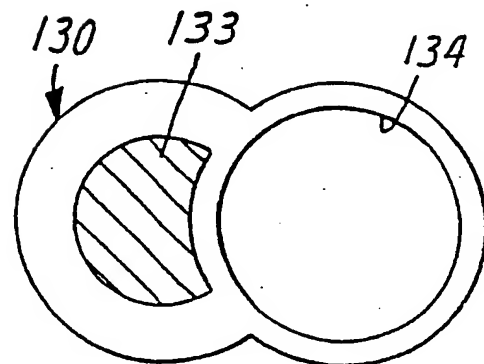


FIG. 13

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US90/05312

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³ According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5): A61F 5/04; A61F 2/44 US CL.: 606/61; 623/17				
II. FIELDS SEARCHED <div style="text-align: center; padding: 2px;">Minimum Documentation Searched ⁴</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%; border: none; padding: 2px;">Classification System</td> <td style="border: none; padding: 2px;">Classification Symbols</td> </tr> </table> <div style="padding: 5px;"> US 606/60, 61, 72, 73, 96, 97; 603/16, 17; 267/166, 168, 162, 289, 290 </div> <div style="text-align: center; padding: 2px;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁶</div>			Classification System	Classification Symbols
Classification System	Classification Symbols			
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴				
Category ⁸	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸		
X	US, A, 190,061 (MIDELTON) 24 April 1877 See the entire document.	1-38,46-47		
<u>X</u> Y	US, A, 1,486,295 (MULLEN) 11 March 1924 See the entire document.	1-4 1-38		
Y	US, A, 1,905,498 (PFEIFFER) 25 April 1933 See the entire document.	1-38		
Y P	US, A, 4,901,987 (GREENHILL et al.) 20 February 1990 See the entire document.	1-38		
Y	US, A, 1,418,758 (WATKINS) 06 June 1922 See the entire document.	1-38,46-48		
Y	US, A, 4,309,777 (PATIL) 12 January 1982 See the entire document.	1-38		
Y	US, A, 4,349,921 (KUNTZ) 21 September 1982 See the entire document.	39-45		
A, P	US, A, 4,878,915 (BRANTIGAN) 07 November 1989 See the entire document.	1-38,46-48		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁵ * Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>				
IV. CERTIFICATION				
Date of the Actual Completion of the International Search ² 02 NOVEMBER 1990		Date of Mailing of this International Search Report ² 05 FEB 1991		
International Searching Authority ¹ ISA/US		Signature of Authorized Officer ¹⁰ MICHAEL A. BROWN		